

REMARKS/ARGUMENTS

Claims 1-4, 7 and 9-19 are pending in this Application. The Office Action mailed on July 26, 2005, includes the following rejections:

1. Claims 1-4, 7 and 9-19 are rejected under 35 U.S.C. § 112 first paragraph.
2. Claims 1-4, 7 and 9-19 are rejected under 35 U.S.C. § 112 second paragraph.
3. Claims 15-17 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Livesey, et al.
4. Claims 15-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dennis, et al.
5. Claims 15-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gulati, et al.
6. Claims 15-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Tanagho, et al.
7. Claims 15-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Atala.
8. Claims 1-3, 9-14 and 17 are rejected under 35 U.S.C. § 103.

Applicants respectfully address the basis for each of the Action's rejections below.

OATH and DECLARATION

Applicants respectfully submit the correct priority information was provided in paragraph [0002] of the original Application and in the Application Data Sheet. Applicants assert that the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e). Furthermore, Applicants submit a copy of the original Application Data Sheet now labeled Supplemental Application Data Sheet to correct the typographical error in the claim of priority in the oath and declaration. Under 37 CFR 1.76(c) Supplemental Application Data Sheet a may be subsequently supplied prior to payment of the issue fee either to correct or update information in a previously submitted application data sheet, or an oath or declaration under § 1.63. Under 37 CFR 1.76(d) inconsistencies between information that is supplied by both an application data sheet under this section and other documents that the latest submitted information will govern notwithstanding whether supplied by an application data sheet, an amendment to the specification, a designation of a correspondence address, or by a § 1.63 or § 1.67 oath or declaration.

Claim Rejections – Claims 1-4, 7 and 9-19 are rejected under 35 U.S.C. § 112 first paragraph.

Applicants respectfully submit that the specification is enabled to support claims 1-4, 7 and 9-19 and complies with 35 U.S.C. § 112 first paragraph. The specification provides multiple detailed examples using sulfobetaines, including sulfobetaines of varying lengths, e.g., SB-10 and SB-16. The structure and characteristics of sulfobetaines are known to the skilled artisan, e.g., a zwitterionic detergent with a hydrophilic carbons tail that stabilizes and solubilizes integral membrane proteins by breaking aggregates. The present specification provides considerable direction and guidance on how to practice the claimed invention and presents working examples. Therefore, all of the methods needed to practice the invention were either well known in the art or disclosed in the specification. (e.g., See, *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

The properties of sulfobetaines are well known in the art and the effects of modifications to the sulfobetaines are also well known in the art. For example, the SB-series detergents, also known as the sulfobetaines (i.e., having a SO₃ group), are a major subset of a broad class of zwitterionic detergents known as the betaines. The betaines are zwitterionic molecules containing, inter alia, a center of positive charge, separated from a center of negative charge. For example, sulfobetaines and modified sulfobetaines and sulfobetaine-like compounds are disclosed in United States Patent Number 6,004,771 issued December 21, 1999 to Thornton. Others have shown that variations in betaine structure produce predictable results with respect to utilization of the betaine.

Therefore, the “representative number of species” presented in the specification are adequately described and are representative of the entire genus of all sulfobetaines. Even if there was variation within the genus, the present specification describes the species to reflect the variation within the genus. See, *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a “physiologically active steroid” and DMSO because “use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.”). As is the case here, the functional recitation of those known compounds in the specification are sufficient.

It is not necessary for the specification to provide every modification and configuration, see, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (Furthermore, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of

knowledge and skill in the art. Noting in *Eli Lilly* modifies this requirement. Further, the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Therefore, the “representative number of species” presented in the specification are adequately described and are representative of the entire genus of sulfobetaines.

The present application provides multiple examples of sulfobetaine as illustrations of the genus. The law is clear that it is not necessary to provide every modification and configuration. Therefore, the present application not only adequately described sulfobetaines having 10 and 16 carbons to demonstrate possession of all sulfobetaines having 10 and 16 carbons. Given the that the structure (e.g., zwitterionic molecules having a center of positive charge, separated from a center of negative charge and a SO₃ group) and characteristics (e.g., zwitterionic detergent) of sulfobetaines are well known in the art, as are the effects of different length carbon chains (2-22) and modifications, the illustrative examples demonstrate possession of the entire genus of sulfobetaines.

As such, the specification satisfies the written description requirement under 35 U.S.C. § 112, first paragraph. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – Claims 1-4, 7 and 9-19 are rejected under 35 U.S.C. § 112 second paragraph.

Claim 14. The Applicants submit that the term “several” is defined as more than one or two but less than many. Therefore, claim 14 has been amended to reflect that definition.

Claim Rejections – Claims 15-17 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Livesey, et al.

The Action rejects claims 15-17 and 19 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,336,616 to Livesey, et al., (“Livesey”), which is said to disclose the claimed invention. Livesey does not anticipate claim 15-17 and 19 of the present invention because it does not teach each and every element of the claim either impliedly or explicitly and the product from the present invention and the product disclosed in Livesey are different. To serve as prior art the reference must still show in as complete detail the present invention as is contained in the claim Livesey does not.

To anticipate a claim, a reference must teach every element of the claim either impliedly or explicitly. See MPEP §2131. As elaborated in *Richardson v. Suzuki Motor Co.*, “[t]he identical invention must be shown in as complete detail as is contained in the claim.” 9 U.S.P.Q.2d 1913,

1920(Fed. Cir. 1987). Further, to anticipate a claim, “a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.” *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). Even though the Product-by-process claims 15-17 and 19 are limited by and defined by the process, determination of patentability is based on the product itself.

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garner*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). The reference clearly fails to do so, as there are distinct differences between the steps in the reference and the present invention.

The product of claim 15-17 and 19 can only be defined by the process steps by which the product is made and the process steps impart distinctive structural characteristics to the final product. For example, the present invention overcomes several disadvantages of current art, namely, loss of function at the donor site, mismatch of nerve cable dimensions between the donor graft and recipient nerve, and the need for multiple surgeries. The present invention is a natural replacement tissue or graft not requiring difficult preparation steps with varying temperatures, radiation and/or harsh chemical or mechanical treatments. The compositions and methods of the invention specifically remove the cellular components without significantly altering the natural extracellular structure (paragraph [0009]). Therefore, the process of the present invention imparts distinctive structural characteristics to the final product.

Livesey discloses a tissue processing solution that contains cryoprotectants to minimize ice crystal damage and dry-protective components, to minimize structural damage alteration during drying. Specifically, the tissue may also be dried and rehydrated prior to transplantation. The product made by Livesey is different from the present invention. Livesey does not disclose a method for preparing a native, cell-free tissue replacement or the product thereof by obtaining a tissue replacement soaking the tissue replacement for at least six hours in a solution having one or more sulfobetaines, washing the tissue replacement in one or more solutions of a buffered salt, extracting with an anionic surface-active detergent and washing the tissue replacement in one or more solutions of a buffered salt. Therefore, Livesey and the present invention are radically different processes and as a result impart distinctive structural characteristics to the respective final products.

Applicants respectfully submit that the Livesey fails to meet the standard of 35 U.S.C. § 102(b) namely, teaching all elements or steps of the claimed invention either explicitly or impliedly and the

present invention and Livesey are different. As such Livesey does not anticipate any of the claims of the present invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

Claim Rejections – Claims 15-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dennis, et al.

The Action rejects claims 15-17 and 19 under 35 U.S.C. § 102(b) as anticipated by Dennis, et al., (“Dennis”) (U.S. Patent No. 6,207,451), which is said to disclose the claimed invention.

Applicants respectfully submit that Dennis fails to meet the standard of 35 U.S.C. § 102(b) namely, teaching all elements of the claimed invention either explicitly or impliedly and the present invention and the reference are different. Thus, the reference does not anticipate any of the claims of the present invention.

The reference must still show in as complete detail the present invention as is contained in the claim. The reference clearly fails to do so, as there are distinct differences between the reference and the present invention. There are clear differences between the present invention and Dennis. Dennis provides a mammalian muscle construct which is developed *in vitro* from cells extracted from mammals. The construct is made outside a living body and in an artificial environment. Furthermore, the mammalian muscle construct includes anchors, which are defined as fragments of biocompatible material with cell adhesion molecules associated therewith, Dennis discloses the pre-incubation of muscle strip in a tube and incubated in a mechanical shaker bath until complete dissociation is observed. Immediately upon complete tissue dissociation, the tubes are centrifuged and the supernatant is aspirated and cells are reconstituted.

At best, Dennis discloses an *in vitro* cell culture or a mass of cells that was complete tissue dissociation and then reconstituted, which is a very harsh mechanical extraction. Therefore, Dennis and the present invention use very different processes and as a result impart distinctive structural characteristics to the respective final products. Dennis does not disclose a native, cell-free tissue replacement or the product thereof by obtaining a tissue replacement soaking the tissue replacement for at least six hours in a solution having one or more sulfobetaines, washing the tissue replacement in one or more solutions of a buffered salt, extracting with an anionic surface-active detergent and washing the tissue replacement in one or more solutions of a buffered salt.

Applicants respectfully submit that Dennis fails to meet the standard of 35 U.S.C. § 102(b) namely, teaching all elements of the claimed invention either explicitly or impliedly and the present invention and the reference are different. Thus, the reference does not anticipate any of the claims of the

present invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

Claim Rejections – Claims 15-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gulati, et al. (“Gulati”)

Applicants respectfully submit that the cited reference fails to meet the standard of 35 U.S.C. § 102(b) namely, teaching all elements of the claimed invention either explicitly or impliedly. Thus, the reference does not anticipate any of the claims of the present invention.

Applicants disagree with the characterization of Gulati. At the very most Gulati discloses the harvesting of a degenerated nerve cell and repeatedly freezing it in N₂ (l). this is clearly a harsh mechanical and thermal treatment. The nerve cell is then placed on a dish of cultured cells (page 120, section 2.3). It is unclear how a single nerve cell on an *in vitro* tissue culture is the same as a native, cell-free tissue replacement. The reference must still show in as complete detail the present invention as is contained in the claim. The reference clearly fails to do so, as there are distinct differences between the reference and the present invention. For example, Gulati does not disclose a tissue replacement product obtained by a soaking an obtained tissue replacement for at least six hours in a solution having one or more sulfobetaines, washing the tissue replacement in one or more solutions of a buffered salt, extracting with an anionic surface-active detergent and washing the tissue replacement in one or more solutions of a buffered salt.

The product of claim 15-17 and 19 can only be defined by the process steps by which the product is made and the process steps impart distinctive structural characteristics to the final product. Therefore the product in Gulati and the product of the present invention are different, made by different process and possess different characteristics to the final product. As there are clear differences between the present invention and the reference, Applicants respectfully submit that Gulati fails to meet the standard of 35 U.S.C. § 102(b). Thus, Gulati does not anticipate any of the claims of the present invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

Claim Rejections – Claims 15-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Tanagho, et al.

Applicants respectfully submit that Tanagho, et al., United States Patent Number 6,371,992 (“Tanagho”) fails to meet the standard of 35 U.S.C. § 102(e) namely, teaching all elements of the claimed invention either explicitly or impliedly. Thus, the reference does not anticipate any of the claims of the present invention.

Tanagho discloses the use of chemical methods use a sodium desoxycholate solution containing

sodium azide to remove cell membranes and intracellular lipids from the intermediate matrix. Tanagho does not disclose a tissue replacement product obtained by a soaking an obtained tissue replacement for at least six hours in a solution having one or more sulfobetaines, washing the tissue replacement in one or more solutions of a buffered salt, extracting with an anionic surface-active detergent and washing the tissue replacement in one or more solutions of a buffered salt. There are distinct differences in the Tanagho process and the present invention as a result there are distinct differences in the products.

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). The product of claim 15-17 and 19 can only be defined by the process steps by which the product is made and the process steps impart distinctive structural characteristics to the final product.

Therefore the product in Tanagho and the product of the present invention are different, made by different process and possess different characteristics to the final product. As there are clear differences between the present invention and the reference, Applicants respectfully submit that Dennis fails to meet the standard of 35 U.S.C. § 102(e). Thus, the reference does not anticipate any of the claims of the present invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(e).

Claim Rejections – Claims 15-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Atala.

Applicants respectfully submit that United States Patent Number 6,376,244 issued to Atala (“Atala”) fails to meet the standard of 35 U.S.C. § 102(e) namely, teaching all elements of the claimed invention either explicitly or impliedly. Thus, the reference does not anticipate any of the claims of the present invention.

The product in Atala and the product of the present invention are different, made by different process and possess different characteristics in the final products. Atala discloses methods for producing a decellularized organ using mechanical agitation methods that involve using a magnetic stir plate and a paddle or a rotator platform. The isolated organ is placed in a container with a suitable volume of fluid and stirred on the magnetic stir plate at a suitable speed. The present invention provides a tissue replacement product obtained by a soaking an obtained tissue replacement for at least six hours in a solution having one or more sulfobetaines, washing the tissue replacement in one or more solutions of a buffered salt, extracting with an anionic surface-active detergent and washing the tissue replacement in

one or more solutions of a buffered salt. The process used in Atala and the present invention are clearly different and impart different characteristics on the respective products. These distinct differences result there are distinct differences in the final products.

Applicants respectfully submit that Atala fails to meet the standard of 35 U.S.C. § 102(e). Thus, Atala does not anticipate any of the claims of the present invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(e).

Claim Rejections – Claims 1-3, 9-14 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Livesey in view of “Detergent properties and Applications”

Applicants respectfully submit that claims 1-3, 9-14 and 17 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below. In order to establish a prima facie case of obviousness, three criteria must be met: (1) the prior art or combined references must teach or suggest all the claim limitations, (2) there must be a reasonable expectation of success, and (3) there must be some suggestion or motivation in the prior art to modify the reference or to combine reference teachings as proposed. MPEP § 2143; *In re Vacek*, 947 F.2d 488 (Fed. Cir. 1991). “The prior art must suggest the desirability of the claimed invention.” MPEP § 2143.01. Both the invention and the prior art references must be considered as a whole. MPEP § 2141.02. Applicants respectfully submit that claims 1-3, 9-14 and 17 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below.

The cited art does not teach or suggest all the claim elements.

Applicants respectfully submit that the cited references do not disclose, teach or suggest all the claim elements of claims 1-3, 9-14 and 17 and as such obviousness cannot be found. MPEP § 2143.03.

As previously discussed, Livesey discloses a collagen-based tissue for transplantation that has been cryoprepared by incubation in a cryoprotective solution and freezing at cooling rates such that minimal functional damage and drying said cryoprepared, processed tissue and incubating said dried cyroprepared, processed tissue in a rehydration solution (e.g., Claim 1). Livesey states the decellularization can be accomplished using a number of chemical treatments, including incubation in certain salts, detergents or enzymes. Livesey discloses the use of CHAPS or similar zwitterionic detergent; however, the incubation lasts for 30 minute to one hour. Similarly, Livesey discloses the use of Sodium Dodecylsulfate (SDS) or similar anionic or nonionic detergent in a sterile PBS base at 7.5 pH for a 30 minute to one hour incubation. (see example 3). However, Livesey does not disclose soaking the tissue replacement for at least six hours in a solution including one or more sulfobetaines, nor does Livesey disclose treating the tissue replacement in a mixture of one or more sulfobetaines with an anionic

surface-active detergent. Livesey relies on harsh freezing to decellularize the processed tissue, not the treatment of the present invention.

Further, the mere fact that references can be combined or modified does not necessarily make the combination obvious unless the prior art suggests the combination. See MPEP § 2143.01; *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Finally, simply stating that a claimed modification of the prior art would have been “obvious to a person of ordinary skill in the art at the time the invention was made” because all aspects of the claimed invention were individually known in the art is not enough to establish a prima facie case of obviousness without some objective reason to combine the teachings. MPEP § 2143.01; *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

There is no teaching or suggestion in the prior art to modify the reference as proposed.

Obviousness can only be found where there is some teaching, suggestion, or motivation to modify a reference in the manner proposed, found either in the prior art itself or in the knowledge generally available in the art. See MPEP § 2143.01; *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992). Further, the mere fact that references can be combined or modified does not necessarily make the combination obvious unless the prior art suggests the combination. See MPEP § 2143.01; *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Again, simply stating that a claimed modification of the prior art would have been “obvious to a person of ordinary skill in the art at the time the invention was made” because all aspects of the claimed invention were individually known in the art is not enough to establish a prima facie case of obviousness without some objective reason to combine the teachings. MPEP § 2143.01; *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

Sigma-Aldrich merely discloses known detergents nothing more. Livesey discloses the use of two detergent, Sodium Dodecylsulfate and CHAPS. There is no teaching, suggestion, or motivation to modify a reference in the manner proposed, found either in the prior art itself or in the knowledge generally available in the art. The skilled artisan knows that just because a compound is listed in an index does not equate to equality in characteristics, e.g., strength, solubility, etc. The compound must remove viable antigenic cells from the structural matrix without damaging the basement membrane complex or the structural integrity of the collagen matrix and the Treatment of the tissue must be at a concentration for a time duration such that degradation of the basement membrane complex is avoided and the structural integrity of the matrix is maintained including collagen fibers and elastin, e.g., see Livesey at column 4, ll. 56-68.

Applicants respectfully submit that there is no teaching, suggestion or motivation found in Livesey and Sigma-Aldrich to combine them in such a way to cure the deficiencies of these references

and render the claims unpatentable under 35 U.S.C. § 103(a).

There is no expectation of success.

In order to establish a prima facie case of obviousness based on a combination of references, there must be a reasonable expectation of success. For the reasons stated above, Applicants respectfully submit that a person of ordinary skill in the art would have no reasonable expectation of success to modify or combine Livesey and Sigma-Aldrich.

Sigma-Aldrich merely discloses known detergents; nothing more. Given that the compound must remove viable antigenic cells from the structural matrix without damaging the complex or the structural integrity of the matrix, the skilled artisan has no guidance as to which compounds in the Sigma-Aldrich product list would have the desired characteristics, nor at what concentration or duration. As such there could be no expectation of success. Livesey does not overcome that deficiency.

Accordingly, Applicants respectfully submit that claim 1-3, 9-14 and 17, are not obvious over Livesey and Sigma-Aldrich and are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim 13 and 23-26 be withdrawn.

Claim Rejections – Claims 4, 7 and 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Livesey in view of Atala

Applicants respectfully submit that claims 4, 7 and 18 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below. In order to establish a prima facie case of obviousness, three criteria must be met: (1) the prior art or combined references must teach or suggest all the claim limitations, (2) there must be a reasonable expectation of success, and (3) there must be some suggestion or motivation in the prior art to modify the reference or to combine reference teachings as proposed. MPEP § 2143; *In re Vacek*, 947 F.2d 488 (Fed. Cir. 1991). “The prior art must suggest the desirability of the claimed invention.” MPEP § 2143.01. Both the invention and the prior art references must be considered as a whole. MPEP § 2141.02. Applicants respectfully submit that claims 1-3, 9-14 and 17 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below.

The combination does not teach, suggest or motivate the Applicants’ claimed invention. Livesey as discussed, *supra* and incorporated herein by reference, discloses, a tissue processing solution that contains cryoprotectants to minimize ice crystal damage and dry-protective components, to minimize structural damage alteration during drying. Additionally, the tissue may also be dried and rehydrated prior to transplantation. Atala as discussed, *supra* and incorporated herein by reference, discloses,

methods for producing a decellularized organ using mechanical agitation method involves using a magnetic stir plate and a paddle or a rotator platform. A case of obviousness has not been established as the cited references lack support for the teaching of all of the elements of the present invention in all of the rejected claims, lacks a reasonable expectation of success, and lacks the motivation or suggestion to combine the elements. As such the rejection fails.

Accordingly, Applicants respectfully submit that claim 4, 7 and 18, are not obvious over Livesey and Atala and are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim 4, 7 and 18 be withdrawn.

Conclusion

In light of the remarks and arguments presented above, Applicants respectfully submit that the claims in the Application are in condition for allowance. Favorable consideration and allowance of the pending claims 1-4, 7 and 9-19 are therefore respectfully requested.

Applicants believe no fees are due at this time. If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: December 23, 2005.

Respectfully submitted,



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